SUPPORT FOR THE AMENDMENTS

Claims 1-39 were previously canceled.

Claims 56-62 and 66-68 are canceled herein.

Claim 46 has been amended.

The amendment of Claim 46 is supported by the specification at page 11, lines 1-7.

No new matter has been added by the present amendments.

REMARKS

Claims 40-55, 63-65, 69, and 70 are pending in the present application.

The rejection of Claims 46-52 and 56-65 under 35 U.S.C. §103(a) over Abraham in view of Hsu, Ghai et al, and Yokozawa et al is respectfully traversed.

Applicants submit that the differences between the claimed invention and the cited prior art is that (i) none of the references disclose or suggest the benefits flowing from the combined use of components (a) and (b) and (ii) none of the references disclose or suggest the specifically claimed weight ratio of (a) to (b).

In making this rejection, the Examiner points to composition code (D) appearing in Table 1 of Abraham as containing ferulic acid, caffeic acid, and chlorogenic acid. Further, the Examiner points to Table 2 of Abraham and asserts that the supplement identified as composition code (D) is added to coffee, composition code (C). Be that as it may, the Examiner acknowledges that Abraham fail to disclose or suggest the administration of such a composition for the treatment or prevention of hypertension.

In an attempt to compensate for this deficiency, the Examiner asserts that Hsu discloses treating hypertension using the herb Crataegus, which contains the active ingredients chlorogenic acid and caffeic acid. The Examiner further references Yokozawa et al as disclosing that caffeic acid and its derivatives are effective for treating hypertension.

Applicants submit that, *at best*, Hsu provides motivation for administering a composition containing chlorogenic acid and caffeic acid to treat hypertension. However, there is no such motivation to add ferulic acid to this composition and to expect the same result. In this regard, it should be noted that the Examiner has not offered any evidence as to the effect of ferulic acid on hypertension. Further, Abraham only relates to the administration

of the compositions appearing in Table 1 to determine their anti-genotoxic effects. At no point does the art of record disclose the co-administration of ferulic acid *with* caffeic acid and/or chlorogenic acid (the compound or the genus) to prevent or treat hypertension or high blood pressure. Ghai et al is merely cited as disclosing processed food, or foods fortified with nutraceuticals and methods of adjusting the combination and level of these nutraceuticals. However, no reference is given in Ghai et al of ferulic acid, caffeic acid and/or chlorogenic acid.

With respect to the first difference, Applicants submit that this deficiency in the art of record is important and evidence for the same is provided in the Examples of the present application. Specifically, Applicants wish to direct the Examiner's attention to the experimental data set forth in Table 1 (page 15) of the present application, which shows the clear advantages of co-administration of ferulic acid with caffeic acid and/or chlorogenic acid. By comparing Test Plots 4-6 to Test Plots 1-3 and looking at the 1 hour point it is clear that the co-administration of ferulic acid with caffeic acid and/or chlorogenic acid is clearly greater than the additive values of the individual administration of these compounds, thus providing evidence of synergism.

The Examiner is reminded that as set forth in MPEP §716.02(a) "greater than expected results are evidence of nonobviousness." Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (i.e., demonstrating "synergism"). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989).

With respect to the second difference, it is the Examiner's position that Ghai et al provides motivation to adjust the combination and level of nutraceuticals in a supplement or

in food products to achieve added nutritional or therapeutic benefit. However, it should be noted that there is no specific motivation provided in Ghai et al, Hsu, Abraham or Takazawa et al as the specific weight ration presently claimed or the effect derived therefrom. Therefore, at best, these combined disclosures would provide motivation to experiment or could be viewed as making it "obvious to try" to arrive at the present invention. However, "obvious to try" has long been held *not* to constitute obviousness. *In re O'Farrell*, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988). A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. *In re Deuel*, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995).

The proper standard for determining obviousness is whether the art itself discloses or suggests all the limitations of the claimed invention. Indeed, MPEP §2142 states: "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation... to modify the reference... Second, there must be a reasonable expectation of success. Finally, the prior art reference... must teach or suggest all the claim limitations." Applicants submit that the disclosures of Ghai et al, Hsu, Abraham or Takazawa et al, fail to meet this threshold test as there is simply no motivation to arrive at the claimed weight ratio.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejection of Claims 46-52 and 56-65 under 35 U.S.C. §112, first paragraph (written description – new matter), is respectfully traversed.

The Examiner alleges that the amendment to Claim 46 of the '694 application introduces new matter and alleges that there is no support for the exclusion of unsupplemented food. Applicants disagree with this allegation by the Examiner. Applicants

submit that the specification provides ample support for the specific selection of food that is to be supplemented with the recited components. For example, page 5, lines 10-13 of the specification recites: "Another aspect of the present invention, provides *a food containing or supplemented to contain* the above-described components (a) and (b)." From this disclosure, the specification provides clear support for the addition (i.e., supplement) of components (a) and (b) to a food that is unsupplemented to thus obtain the required ratio of components.

Accordingly, Applicants request withdrawal of this ground of rejection.

The rejection of Claims 46-52 and 56-65 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Applicants have amended Claim 46 to specify that the ratio is a weight ratio. Further, Claims 56-62 have been canceled.

Applicants request withdrawal of this ground of rejection.

The obviousness type-double patenting rejection of Claims 40-42 and 56-70 over Claims 1-11 of U.S. Patent No. 6,310,100 (apparently in view of Yokozawa et al) is respectfully traversed.

Applicants submit that this ground of rejection is without merit as the claims of U.S. Patent No. 6,310,100 fail to include ferulic acid in addition to caffeic acid and/or chlorogenic acid, which is required in the claimed invention. The Examiner relies upon Claim 5 of U.S. Patent No. 6,310,100 as disclosing the co-administration of ferulic acid with "at least one other anti-hypertensive compound." Such a broad genus disclosure certainly does not put the skilled artisan in possession of either caffeic acid or chlorogenic acid amongst the vast classification of anti-hypertensive compounds. Moreover, even if the skilled artisan were to

select caffeic acid or chlorogenic acid, there is certainly no reasonable basis to conclude that the artisan would envision the results set forth in the present application.

Specifically, as discussed above in regard to the rejection over Abraham in view of Hsu, Ghai et al, and Yokozawa et al, the data set forth in Table 1 clearly show the substantial advantages flowing from the claimed combination as compared to compositions in which only ferulic acid is present (i.e., U.S. Patent No. 6,310,100). In particular, these data show synergism as the one hour time-point. As such, Applicants submit that the claims of the present application are pantentably distinct from the claims of U.S. Patent No. 6,310,100.

Accordingly, withdrawal of this ground of rejection is requested.

The provisional obviousness-type double patenting rejection of Claims 40-70 over Claims 1-6 of U.S. 11/209,672 is respectfully traversed.

The Office's records (see the Patent Information Retrieval System) for U.S. Application No. 11/209,672 show that this application was officially abandoned on October 20, 2006. Therefore, this rejection should be withdrawn.

Applicants submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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